

Wisconsin Department of Regulation & Licensing

Mail To: P.O. Box 8935
Madison, WI 53708-8935

FAX #: (608) 261-7083
Phone #: (608) 266-2112

1400 E. Washington Avenue
Madison, WI 53703

E-Mail: web@drl.state.wi.us
Website: <http://www.drl.state.wi.us>

APPLICATION INFORMATION FORM

ATTENTION

IMPORTANT INFORMATION PLEASE READ

Enclosed is the application packet you recently requested from the Wisconsin Department of Regulation and Licensing.

To avoid any unnecessary errors, take a moment to review the entire application packet before you begin to complete your application.

We will mail you a check sheet within 10-15 working days after receipt of your application in this office. The check sheet will include an identification number that allows you to check the status of your application by calling the **Interactive Voice Response System, (608) 261-7925**. The Interactive Voice Response System will inform you of any requirements not met. You may also check the status of your application on our web-site: <http://www.drl.state.wi.us>. Look under "Applicant Services."

It is your obligation as an applicant to see that the items listed as "Is Required" are forwarded to the Department of Regulation and Licensing. The Department will not contact other agencies or jurisdictions for information/documents to complete your application. We will update check sheets within 3-5 working days of receipt of documents. An application is not considered complete until we receive all the required documents and fees.

Once your application is complete, check the department's web-site: <http://www.drl.state.wi.us>. Look under "Business/Professional License Lookup" for your official credential number and grant date.

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PHARMACY EXAMINING BOARD

APPLICATION FOR MANUFACTURER OF DRUGS LICENSE

(PLEASE TYPE OR PRINT IN INK)

APPLICANT (individual, partnership, association or corporation):

DBA (name or title under which business is operated):

BUSINESS ADDRESS (number, street, city, zip code):

TELEPHONE NO.:

() -

NAME OR OWNER OR NAME & TITLE OF ALL PARTNERS OR CORPORATE OFFICERS AND % OF OWNERSHIP

Name

Percentage

GIVE NAMES OF PERSONS PERSONALLY SUPERVISING SCIENTIFIC OR TECHNICAL OPERATIONS IN THE PLANT ALONG WITH A DETAIL OF THE SCIENTIFIC AND THE TECHNICAL TRAINING INCLUDING COLLEGES ATTENDED AND SCHOLASTIC DEGREES. (Attach an extra sheet if necessary)

APPLICATION FEE:

Make check payable to Department of Regulation and Licensing. Attach check to this application.

\$ 53.00

For Receipting Use Only

Wisconsin Department of Regulation & Licensing

ANSWER THE FOLLOWING QUESTIONS:

1. INDICATE YOUR FOOD & DRUG ADMINISTRATION REGISTRATION NUMBER AND EXPIRATION DATE.
____ YES ____ NO
Registration Number _____ Expiration Date _____
2. IF APPLICABLE, INDICATE YOUR DRUG ENFORCEMENT ADMINISTRATION REGISTRATION NUMBER AND EXPIRATION DATE.
____ YES ____ NO
Registration Number _____ Expiration Date _____
3. HAVE ANY OF THE PRINCIPALS PREVIOUSLY BEEN LICENSED BY THE WISCONSIN PHARMACY EXAMINING BOARD?
____ YES ____ NO If yes, give name and location: _____
4. HAVE ANY OF THE PRINCIPALS EVER BEEN CHARGED WITH A FELONY OR MISDEMEANOR?
____ YES ____ NO If yes, attach a sheet providing details about the crime, including date of conviction, penalty and a copy of the court documents. (Please do not give details on minor traffic charges, but do include information relating to Driving While Intoxicated (DWI) charges.)
5. HAVE ANY OF THE PRINCIPALS HAD THEIR PHARMACISTS, PHARMACY, MANUFACTURER OR DISTRIBUTOR LICENSE SUSPENDED, REVOKED OR REPRIMANDED IN THIS OR ANY OTHER STATE?
____ YES ____ NO If yes, attach a sheet providing details about the action, including the name of the credentialing agency and date of action.
6. DO ANY OF THE PRINCIPALS HAVE A PHARMACY, PHARMACIST, MANUFACTURER OR DISTRIBUTOR LICENSE NOW SUBJECT TO DISCIPLINARY PROCEEDINGS IN THIS OR ANY OTHER STATE?
____ YES ____ NO If yes, attach a sheet providing details about pending action, including the name of the agency and status of action.
7. HAVE ANY OF THE PRINCIPALS OR APPLICANT CONDUCTED A SIMILAR BUSINESS IN ANY OTHER STATE?
____ YES ____ NO If yes, complete below:
LICENSING STATE LICENSE NUMBER

LIST PRESCRIPTION OR NON-PRESCRIPTION DRUGS AND CONTROLLED SUBSTANCES MANUFACTURED OR REPACKAGED WITH MANUFACTURERS TRADE NAME AND GENERIC NAME BELOW: (Attach an extra sheet if necessary.)

Trade Name

Generic Name

_____	_____
_____	_____
_____	_____
_____	_____

AFFIDAVIT OF APPLICANT

The undersigned, having been duly sworn on oath, states that the facts and statements herein contained are true and correct based upon personal knowledge of the undersigned.

Applicant Signature _____

Date _____

State of _____

County of _____

Subscribed and sworn before me this _____ day

of _____, 20____

by _____

(applicant)

S E A L

Notary Public, State of _____

My Commission Expires: _____

NOTE: This affidavit must be signed by the applicant in the presence of the notary public on the same date.

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ADDENDUM TO APPLICATION – BUSINESS ENTITIES

Information requested is required for processing.

EMPLOYER IDENTIFICATION NUMBER. Your employer identification number must be submitted with your application on this form. If you do not have a social security number you must submit a statement under oath or affirmation. If your social security number or a statement is not provided, your application will be denied.¹ A form for submitting a statement that you do not have a social security number is available from the department.

(Please Print)

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FEIN

Business Entity Name

Type of Credential applying for

The Department may not disclose the employer identification number collected above except to the Department of Workforce Development for purposes of administering the child and spousal support program,² to the Department of Revenue for the purpose of determining whether you are liable for delinquent taxes,³ and to the federal Healthcare Integrity and Protection Data Bank for the purpose of reporting adverse actions against health care practitioners.⁴

DELINQUENT STATE TAXES; DELINQUENT SUPPORT

All applications for professional credentials are checked to determine whether the applicant is liable for delinquent state taxes. Under state law, the department must deny your application if you are liable for delinquent Wisconsin taxes.⁶ If you are liable for delinquent state taxes, pay the delinquent amount before the application process is completed. Retain proof that you have satisfied the tax delinquency. If you have any questions about payment of delinquent taxes, please contact your nearest Department of Revenue office or call (608) 261-6249. An application may be denied or a credential suspended if an applicant or credential holder is delinquent in paying support or fails to comply with a subpoena or warrant issued by the department of workforce development or a county child support agency related to support or paternity proceedings.²

#2552 (11/02)

¹ Section 440.03 (11m), Wis. Stats.

² Sections 49.22, and 440.13, Wis. Stats.

³ Section 440.12, Wis. Stats.

⁴ Health Insurance Portability and Accountability Act (HIPAA) of 1996

⁵ Section 440.14, Wis. Stats.

⁶ Section 440.12, Wis. Stats.

This form is authorized by secs. 440.12 and 440.14, Wis. Stats. Making a false statement in connection with this application may result in revocation or denial.

Committed to Equal Opportunity in Employment and Licensing

Wisconsin Department of Regulation & Licensing

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CONVICTIONS AND PENDING CHARGES

If you have been convicted of a crime or have criminal charges pending against you, complete this form and return it with your application. Include a \$6.00 Crime Information Bureau report fee in addition to your original application fees.

The Fair Employment Act (sections 111.31-111.395, Wis. Stats.) prohibits employment discrimination on the basis of conviction record or arrest record unless the circumstances of the conviction or arrest substantially relate to the circumstances of the particular job or licensed activity. The information requested on this form will be used to determine whether your application should be granted, approved with limitations, or denied. The information you provide on this form may be verified against criminal information records. Omission of information on this form will be considered a false statement on an application.

Profession you are applying for: _____

Last Name	First Name	MI	Former / Maiden Name(s)
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Your Street Address (number, street, city, state, zip) _____

Mail To Address (if different) _____

Date of Birth	Social Security Number
____ month ____ day ____ year	_____

Information helps us identify your record, but is voluntary. It is not available to the public.

Ethnic/gender information is required to check criminal information records. Sex: ☐ M ☐ F Ethnic: ☐ White, not of Hispanic origin ☐ Black, not of Hispanic origin ☐ Hispanic ☐ American Indian or Alaskan ☐ Asian or Pacific Islander ☐ Other

1. List all other names used: _____

2. List all felonies, misdemeanors, and other violations of state or federal law of which you have ever been convicted, in this state or any other, whether the conviction resulted from a plea of no contest or a guilty plea or verdict. For each, list the date and location of the conviction. Please include all convictions that involved alcohol or other drug use, including convictions for operating while intoxicated. Do not include municipal ordinance violations or other traffic offenses.

It is your responsibility to submit certified copies of the police report or criminal complaint, judgment of conviction and sentencing, and verification of your compliance with all terms of each sentence, including chemical dependency assessments if ordered by the court. If the conviction is old and records have been destroyed, you must submit a written description of each offense, along with an explanation of the penalties imposed and verification that you completed all requirements.

OFFENSE

DATE

CITY/STATE

Attach additional sheet(s) if necessary.

Wisconsin Department of Regulation & Licensing

3. Have you ever been sentenced by a court to participate in an alcohol or other drug assessment, treatment or counseling program? YES NO MO/YR COMPLETED
☐ ☐ _____
Did you successfully complete the program? ☐ ☐ _____
Please attach the certificate of completion/discharge summary.

- (Check all that apply)
4. Have you ever been sentenced to: YES NO MO/YR COMPLETED
☐ Probation ☐ ☐ _____
☐ Parole ☐ ☐ _____
☐ Ordered to pay restitution ☐ ☐ _____
Did you successfully complete one of the above as ordered by the court? ☐ ☐ _____

If you are currently on probation or parole, you must request your probation/parole officer to send a letter describing your current probation/parole requirements and your compliance with supervision.

5. List all felonies, misdemeanors, or other violations of state or federal law for which you have been arrested and which are pending. Submit a copy of the police report/criminal complaint for each of the following pending charges.

<u>PENDING CHARGE</u>	<u>DATE OF ARREST</u>	<u>LOCATION OF ARREST (city/state)</u>
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Comments you wish to make regarding your convictions or pending charges. Attach another sheet if necessary.

AFFIDAVIT OF APPLICANT

I state that I am the person referred to in this document and that all the information which I provided above is true in every respect. I understand that false or forged statements made in this document in connection with my application for a credential, or failing to provide relevant information, may be grounds for denial of the application, revocation of the credential granted to me, or criminal prosecution. This document must be signed before a notary public.

Signature _____	Date _____
-----------------	------------

Signed and sworn before me this _____ day of _____, 20 _____.

Signature of Notary Public _____	Date _____
----------------------------------	------------

My commission (is permanent) _____ expires _____.

SEAL

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NOTICES

TIME FOR REVIEW AND DETERMINATION OF CREDENTIAL APPLICATIONS

Generally, a credentialing authority is required to make a determination on an original application for a credential within 60 business days after a completed application is received.^a An application is completed when all materials necessary to make a determination on the application and all materials requested by the licensing authority have been received.

PROCEDURES ON APPLICATION DENIAL

An applicant who receives a notice of denial may request a hearing to challenge the denial by filing a request with the appropriate board or the department within 45 days after the mailing of the notice of denial. The request must contain the applicant's name and address, the type of license sought, the reasons why a hearing is requested and a description of the mistake the applicant believes was made, if the applicant claims that the denial was based on a mistake of fact or law. Hearing procedures are specified in ch. RL 1 of the Wisconsin Administrative Code. A copy of ch. RL 1 is available at most public libraries, on the Internet through the index at <http://www.legis.state.wi.us/rsb/code/rl/rl.html> and may also be obtained from the department.

MAILING ADDRESS AND CHANGE OF ADDRESS

Credential holders may use a business address as a mailing address for department mail. A change of address must be reported to the department within 30 days.

PERSONALLY IDENTIFIABLE INFORMATION: USE AND AVAILABILITY

Information collected on an application form is required and will be used to determine eligibility for a credential or examination. It is not likely that the department will use information collected by these forms for other purposes.

Credentialing is a public process with a goal of identifying those competent to protect the public. The name, city, and status of credential holders are accessible at the Department's website at <http://www.drl.state.wi.us/> under "Credential Holder Query." Information collected on application and examination forms is available for inspection to the public under Wisconsin laws governing public records.

AMERICANS WITH DISABILITIES ACT

The Department complies with the Americans With Disabilities Act of 1990. The Department will make reasonable modifications to policies, practices and procedures when modifications are necessary to avoid discrimination on the basis of disability and will make reasonable accommodations necessary to provide a qualified individual with a disability with equal access to department programs.

Communications and examinations: Individuals who need auxiliary aids for effective communication in programs and services or who wish to request special accommodations for examinations, please call (608) 266-2852 or TTY at (608) 267-2416.

Complaints: Procedures for alleging violations of the Americans with Disabilities Act of 1990 may be obtained by calling the Department's ADA Coordinator at (608) 266-8608 or TTY at (608) 267-2416.

#1988 (Rev. 11/02) ss. 15.04 (1) (m), 19.35, Stats.

^a Section RL 4.06 of the Wisconsin Administrative Code

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Website: http://www.dtl.state.wi.us

FOR OFFICE USE
License #: _____
Date Granted: _____
To DOE: _____

MANUFACTURER SELF-INSPECTION REPORT

Current Wisconsin Manufacturer
License Number (if applicable) _____

APPLICANT NAME: _____

DBA NAME: _____

ADDRESS: _____

TELEPHONE: () _____

HOURS: Mon-Fri: _____ Sat _____ Sun _____

____ Change in Ownership

____ New Location

____ New Owner

PERSONNEL

Name of Owner(s):

Chapter Phar 12 Wisconsin Administrative Code (Manufacturer Requirements)

PLACE INITIALS CERTIFYING COMPLIANCE.

Phar 12.03

____ The establishment is registered with the food and drug administration and complies with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

____ *Note-attach copy of the most current food and drug administration inspection.*

____ If applicable, the establishment is registered with the drug enforcement administration and complies with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

____ *Note-attach copy of the most current drug enforcement administration inspection.*

____ A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

Phar 12.04 1

____ The establishment meets the current standards of 21 USC 351 and 352 and 21 CFR 210 and 211.

Wisconsin Department of Regulation & Licensing

AFFIDAVIT

I, the applicant, state that all statements herein contained are each and all strictly true in every respect. I have read the applicable Wisconsin State Statutes and Administrative Code concerning Manufacturer Requirements, am familiar with its provisions, and if granted a license, agree that I will abide by all of said provisions. I understand that false or forged statements made in connection with this application may be grounds for denial or revocation of the Manufacturer's License.

Signature of Applicant

State of _____ County of _____

Subscribed and sworn to before this _____ day of _____, 20____, by _____

(Applicant name)

Signature of Notary Public

SEAL

Date Commission Expires

NOTE: This affidavit must be signed by the applicant in the presence of the notary public on the same date.

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PHARMACY EXAMINING BOARD

BUSINESS MODELS AND THE REQUIREMENTS FOR LICENSURE

(PHARMACY, PRESCRIPTION DRUG DISTRIBUTOR AND DRUG MANUFACTURER)

Drug Manufacturers:

1. Drug or device manufacturing facilities which are located within the state of Wisconsin are required to obtain a manufacturer's license from the board. If the Wisconsin facility also directly distributes these pharmaceuticals at wholesale a distributor's license is also required.
2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.
3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.
4. A distributor's license would be required for an out-of-state manufacturing facility if it engages in the wholesale distribution of prescription drugs or devices in this state from that manufacturing facility.
5. Any other distribution facility located in-state or out-of-state, whether or not owned by the manufacturer, must be licensed as a distributor if it engages in the wholesale distribution of prescription drugs or devices in this state.
6. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity. This means that a manufacturer can ship prescription drugs and devices from its manufacturing facility (in-state or out-of-state) to a distributor facility (in-state or out-of-state) which are both under common ownership or control without the need for the manufacturing facility to also be licensed as a distributor.

Prescription Drug Distributors:

1. A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. [See, sec. 450.07 (3), Wis. Stats.]. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.
2. Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.

State of Wisconsin Department of Regulation & Licensing

3. Distribution by company A of prescription drugs under the label of company B. A distributor's license is required in this state for the facility that distributes a prescription drug into (or in) Wisconsin, irrespective of where that facility is located. The fact that the distributor (company A) may also manufacture the product under a different label does not require a separate manufacturer's license unless the facility is physically located in this state. Nor does Wisconsin law require that the entity whose label is being utilized (here, company B) be licensed as a distributor or manufacturer in this state.
4. Company A recently acquired ownership of certain prescription and OTC products previously distributed by company B along with the right to use company B's name. The products, themselves, will continue to be distributed from facilities which are currently licensed as wholesale distributors in this state. Company A does not own or operate any of the licensed distributor facilities. Company A is not required to obtain a wholesale distributor's license from this state. A distributor's license is required in Wisconsin for each facility which distributes prescription drugs at wholesale. Although the ownership of the prescription medications being distributed at wholesale has changed, the owner of the licensed distributor facilities has not. Mere "ownership" of prescription drugs or devices being distributed does not require a distributor's license.
5. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity.

Out-of-State Pharmacies:

1. This state does not require a Wisconsin pharmacy license be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state. Wisconsin does not license out-of-state pharmacies at this time.

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APPLICATION PACKET ADDENDUM (INTERNET)

DRUG MANUFACTURER

For the application packet that you have just downloaded, there are additional materials needed.

Please complete this form and fax it to the number listed above. Once the form is returned we will mail the additional items to the address you have provided. If you prefer, you can mail this form directly to the Department of Regulation and Licensing, P.O. Box 8935, Madison, WI 53708.

Please indicate on this form if you have downloaded the Wisconsin Statutes and Code Book for this profession. ☐ Yes ☐ No

PLEASE PRINT OR TYPE

Full Name

Daytime Phone Number

Street Address

PO Box

City, State, Zip

Thank you.

#2612 (4/03)